

## **REMARKS**

Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested.

### **I. Status of the Claims**

Claims 1 – 28, 91, 94, and 95 are currently pending in this application and are at issue. Groups I and II have been rejoined and are pending in this application. Applicants thank the Examiner for rejoining Groups I and II as well as Groups VII/VIII and Groups XIII/XIV in the non-elected inventions. Claims 29 – 34 are withdrawn. Claims 35 - 90, 92- 93, and 96 - 99 are canceled without prejudice. No new matter has been added.

### **II. Rejections under 35 U.S.C. 103(a)**

#### **Schacht**

Claims 1-4, 15-28, 91, 94, and 95 are rejected as obvious under 35 U.S.C. §103(a) over Schacht (U.S. Pat. 6,933,328). The Examiner states that Schacht discloses a crosslinkable prepolymer, a polymer, and a mineral biologically active component for bone implant, and that compositions containing a bone substitute are taught in Schacht Examples 7 and 21. The Examiner then argues that it would be obvious to modify the Schacht process of placing the curable composition on top of an allograft filling and apply a mixture of the curable composition and allograft to form the compositions of the presently claimed invention.

Applicants respectfully traverse. The present claims would not have been obvious in view of Schacht since it would not have been obvious to modify Schacht, which teaches a composition having both a biodegradable region and a hydrophilic region, to form a composition claimed in the present invention. In particular, the Schacht crosslinkable multifunctional prepolymer comprises: (1) a biodegradable region selected from the group consisting of poly- $\alpha$ -hydroxyacids, polyesters, polyaminoacids, polyorthoesters, and mixtures thereof or polyacetals, and (2) a polymerizable region having at least two polymerizable end groups. None of the polymers taught by Schacht as useful for the biodegradable region include a degradable anhydride linkage as in the presently claimed invention, but contain ether and/or ester linkages. In particular, in Examples 7 and 21, Schacht teaches a polyester

methacrylate and polyester bismethacrylate. These polymers contain ester linkages, not anhydride linkages. The two are distinct chemical moieties with distinct properties. Since neither of the esters form an anhydride polymer, the Schacht polymer does not teach the polymers of the present invention. Similarly, the other polymers exemplified by Schacht or those obvious to one of ordinary skill in the art in view of Schacht's teaching would not include the diacids or multifunctional acids combined with a carboxylic acid to form an anhydride. While Schacht mentions polyanhydrides in a list of polymers suitable for the biodegradable region (col. 6, line 34), he does not describe either their synthesis or further describe their use in the invention. Schacht simultaneously teaches the anhydride polymers described by Shastri have the disadvantage that they generate acidic compounds *in vivo* such that any therapeutic agents having reactivity with the anhydride linkage must be incorporated indirectly. (See Schacht, col. 2 lines 42-45 and col. 3, line 15). Therefore, taken in the entirety, the Schacht application does not sufficiently teach the use of polyanhydrides in combination with a bone substitute to form the curable admixture of the presently claimed invention. It would not have been obvious to one of ordinary skill in the art to use a polyanhydride in place of a polyester or other polyacetals as taught by Schacht, due to the different chemical properties expected when working with these polymers.

Schacht teaches that various therapeutic agents or mineral biologically-active components can be added to his composition (see col. 3 line 60 – col. 4 line 5). However, this teaching would not have made the compositions of the present invention obvious. There is no suggestion in Schacht that the additional agent added to the polymers could also be added to a different polymer containing an anhydride of a diacid or multifunctional acid and a carboxylic acid molecule.

Additionally, the compositions of the present invention have new and useful properties compared to the Schacht polymers. Schacht does not provide a composition with sufficient support and resistance in either the short or the long term--it does not provide adequate rigidity in the short term and does not have sufficient bone regenerating capacity. An implant made from the Schacht polymer is not stable, exhibits significant micro-movements, and is not immediately load-bearing. (See specification para [0014]). In contrast, the presently claimed invention comprises a composition that forms an immediately hardening composition containing a resorbable bone substitute. Examples 11 - 12 in the present application incorporate mechanical strength data, demonstrating that the compositions of the present invention have sufficient properties to be immediately load bearing.

**Schacht in view of Anseth or Shastri**

Claims 5 – 14 are rejected as obvious under 35 U.S.C. §103(a) over Schacht in view of Shastri et al. (US 5,837,752) or Anseth et al. (US 5,902,599). The Examiner argues that, while Schacht does not teach the methacrylic acid dianhydride polymer, the curable polymers described by Shastri or Anseth could be combined with the teaching of Schacht.

Applicants respectfully traverse. As discussed above, Schacht does not teach compositions containing anhydride polymers; therefore, there is no suggestion or motivation to combine the Schacht polymer with methacrylic acid dianhydride polymer.

Further, Schacht teaches polymers that 1) overcome the problem of acidic polymer matrices, 2) are based on liquid capped prepolymers, and 3) have controlled leaching time (see Schacht col. 3 lines 12 – 26). Schacht particularly points out the ‘problem’ present in the polymers described by Shastri and clearly states that the polymers as described by Shastri have the disadvantage that they generate acidic compounds in vivo such that any therapeutic agents having reactivity with the anhydride linkage must be incorporated indirectly. (See Schacht, col. 2 lines 42-45 and col. 3, line 15). Anseth, like Shastri, teaches the use of anhydride prepolymers and, according to the teaching of Schacht, will suffer from the same disadvantage as Shastri.

To overcome these stated problems, Schacht uses a different polymer chemistry based on biodegradable ester and ether linkages. Since Schacht particularly teaches that he has solved the problem associated with the use of anhydride polymers by instead using ester and/or ether polymers, a person of ordinary skill in the art would not find that the compositions of Schacht and the compositions of either Anseth or Shastri could be combined. This person would not be motivated to use the anhydrides Schacht clearly teaches against (i.e., methacrylic acid dianhydride), either alone or in combination with a bone substitute.

**Anseth in view of Schacht**

All claims are rejected under 35 U.S.C. §103(a) as obvious over Anseth in view of Schacht. The Examiner states that Anseth teaches that the biodegradable polymer networks can be combined with fillers, reinforcing materials, and/or other materials needed for a particular implant, and this teaching can be combined with the teaching of bone substitutes in Schacht.

Applicants respectfully traverse. The teaching of Anseth, namely that the prepolymers can be combined with fillers, reinforcement materials, radio imaging materials, excipients, or other materials as needed for a particular implant application, would not have made the present invention, requiring a curable admixture of a bone substitute and a crosslinkable prepolymer, obvious. The terms filler and excipient are both indicative of inactive components that do not contribute to the function or structure of the implant or graft material to which they are added. A bone substitute is distinguished from a filler or excipient in that it acts as an osteoconductive scaffold for newly regenerated/generated bone (see para. [0004]). Also, the teaching of the addition of a radio imaging material does not teach or suggest forming an admixture with a bone substitute. Additionally, the teaching of adding a “reinforcement material” or “other materials as needed” is undefined and vague. Neither of these terms is described by Anseth. Therefore, it would not have been obvious to form an admixture of a bone substitute with the prepolymer described by Anseth based on this teaching.

While Schacht does provide motivation for combining a composition having a biodegradable region and a polymerizable region with therapeutic agents or mineral biologically-active components, such a teaching does not suggest combining a bone substitute with the prepolymer described by Anseth. As discussed above, Schacht teaches against the use of the non-analogous prepolymers described in Anseth. Further, while Schacht mentions adding additional agents to the polymer, he does not teach or suggest forming a curable admixture of the polymer and active component as in the claimed invention.

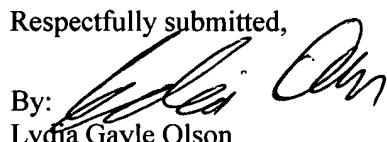
Additionally, the present invention provides unexpected results over both the Anseth and Schacht patents, which further indicates the non-obviousness of the present claims. Particularly, the present invention provides new materials which immediately harden and provide sufficient mechanical strength upon hardening to become load bearing to provide immediate support for the installation of a crown using a dental implant, and immediate functionality for an artificial tooth (i.e., the crown) (see para. [0015]). The mechanical strength provided by the polymers of the present invention, which provide immediate functionality is similarly useful in areas such as spinal fusion. (See para. [0161]). In contrast, the polymers as described by Schacht or by Anseth, with or without the addition of a filler etc, do not provide immediately load-bearing compositions.

**III. Conclusion**

In view of the above amendments and remarks, applicants believe that each of the pending claims in this application is in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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